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TITLE: A Controlled Study Using Acupuncture as an Adjuvant to Treat Chemotherpay-Induced Nausea and Vomiting

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13. ABSTRACT ***(Maximum 200 Words)***

This is a randomized, double blind controlled study designed to assess the effects of Electroacupuncture (EA) on nausea and vomiting induced by chemotherapy in breast cancer patients. The primary aim of this study is to evaluate the usefulness of EA as an adjuvant on N/V in chemotherapy patients who do not respond to conventional antiemetics. Seventy five outpatients will be recruited from the University of Maryland Baltimore (UMB) Cancer Center who have shown refractory to 5-HT_3 antiemetic and randomized into three treatment groups (n=25 per group): (1) EA: 10 Hz, 10 min, (2) EA: 100 Hz, 10 min, and (3) a sham acupuncture control group. Research team personnel have been hired and recruitment began in January 2000. As of August 31, forty-two patients have been screened, six were eligible, and four have consented to go on protocol and have now completed the study. The study has experienced difficulty with obtaining sufficient recruitment due to a relatively small breast cancer patient pool at the UMB Cancer Center. An amendment IRB requesting permission to expand the eligibility criteria to include all cancer chemotherapy patients has recently approved by IRB and DOD, and the expanded recruitment procedure will begin in Oct. 2000.

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INTRODUCTION

Nausea and vomiting (N/V) are significant side effects of cancer chemotherapy which can both affect a patient's quality of life and compromise a physician's ability to deliver adequate doses of effective chemotherapy. The purposes of this study are: 1) to evaluate the effectiveness of EA as an adjunctive therapy for minimizing nausea and vomiting caused by chemotherapy; 2) to compare the effectiveness of two protocols of EA on N/V; and 3) to measure the usefulness of EA in improving the general quality of life of cancer patients. This is a randomized, double blind controlled clinical trial with independent assessment of the effect of Electroacupuncture (EA) on nausea and vomiting induced by chemotherapy in patients who do not respond to 5-HT_3 antiemetics. The specific aims of this study are three-fold: 1) to evaluate the usefulness of EA as an adjuvant on N/V in chemotherapy patients who do not respond to 5-HT_3 antiemetics; 2) to compare the effectiveness of two protocols of EA on N/V; and 3) to document the benefit of EA on improving the general quality of life of cancer patients. Seventy five outpatients recruited from Cancer Center, UMB, who have shown refractory to 5-HT_3 antiemetic, will be randomized into three treatment groups (n=25 per group): treatment group I (EA: 10 Hz, 10 min), treatment group II (EA: 100 Hz, 10 min), and sham control group.

BODY

During the first 3 months of the study, the research personnel have been hired, including research nurses and acupuncturists. Several research team meetings with the PI and co-investigators, physicians and nurses in the Cancer Center, the research coordinator, and the biostatistician have been held. Patient recruitment began in January 2000. As of August 31, there have been forty-two patients screened for the study. Of the forty-two screened, six patients were eligible. Four of the six eligible patients have consented to go on protocol and have completed the study. Of the two eligible patients who chose not to participate, one lived at too great of a distance and was unwilling to travel to the University for the additional appointments necessary for the study while the second patient gave no specific reason for not participating. Complete data have been from the participating patients and the procedures appear to be working quite well, although due to the low enrollment (four subjects total) no analyses have been performed to date. No subjects have withdrawn and no serious adverse events due to acupuncture treatment have been observed.

The study is having difficulty with obtaining sufficient recruitment. One reason has been that the breast cancer patient pool at the Cancer Center has been relatively small. An amendment requesting Institutional Review Board (IRB) permission to expand the eligibility criteria to include chemotherapy patients who are suffering from cancer other than breast cancer has recently been approved by the UM IRB and the Department of Defense. It is hoped that by expanding the pool of participants the study will have a sufficient numbers of participants to complete the project. We believe that expanding the exclusion criteria beyond breast cancer to other cancer patients undergoing chemotherapy will not change the scope of the project, since our primary purpose is to evaluate the effectiveness of acupuncture in relieving chemotherapy induced nausea and vomiting. The primary cancer diagnosis should therefore not matter and the result obtained from the study will continue to potentially benefit breast cancer patient. It is expected that expanding the pool of participants will result in the study having sufficient numbers of participants to complete the project.

KEY RESEARCH ACCOMPLISHMENTS

- Study research personnel have been hired
- Patient recruitment has begun

REPORTABLE OUTCOMES

NA

CONCLUSIONS:

This is an on-going study to investigate the effect of Electroacupuncture (EA) on nausea and vomiting induced by chemotherapy in the cancer patients who do not respond to conventional antiemetics. Research team personnel have been hired. Patient recruitment began in January 2000. However, the patient enrollment has been unexpected slow. This is partially due to relatively small breast cancer patient pool at the UMB Cancer Center. An amendment requesting IRB permission to expand the eligibility criteria to include chemotherapy patients who are suffering from cancer other than breast cancer has recently been approved by the UM IRB and the DOD. The expanded recruitment procedure will start in Oct. 2000. It is hoped that by expanding the pool of participants the study will have a sufficient number of participants to complete the project.

REFERENCES: NA

APPENDICES : NA